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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,126	12/15/2003	Gregory Plowman	034536-0928	2609

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,126	PLOWMAN ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18 and 29-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18 and 29-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 10/4/05 in response to the Office Action of 7/5/05 are acknowledged and have been entered.

Claims 17-18 were pending.

Claims 29-42 have been added by Applicant.

Claims 17-18 have been amended by Applicant.

Claims 17-18 and 29-42 are currently under examination.

The text of those sections of Title 35 U.S.C. code not included in this Office Action can be found in a prior Office Action.

The following Office Action contains NEW GROUNDS of rejections.

Rejections Withdrawn

The rejection of claim 17 under U.S.C. 101, for being drawn to non-statutory subject matter, is withdrawn in view of amendments.

The rejections of claims 17 and 18 under U.S.C. 112, second paragraph, for being vague and indefinite, are withdrawn in view of amendments.

Response to Arguments

The rejection of claims 17-18 and newly added claims 29-42 under U.S.C. 112, first paragraph, because the written description of the invention does not evidence

possession of the invention, is maintained for the reasons of record and the reasons set-forth below.

In the Response filed 10/4/05, Applicants amended claims 17-18 to include references to SEQ ID NO:3 and SEQ ID NO:4. The Response further states that the "...references make it explicit within the claims that AUR1 and/or AUR2 polypeptides have a structural relationship to SEQ ID NO:3 and SEQ ID NO:4."

The response filed 10/4/05 has been carefully considered but is deemed not to be persuasive. The written description in this case only sets forth an isolated antibody or antibody fragment thereof having specific binding affinity to a polypeptide *comprising* SEQ ID NO:3 or SEQ ID NO:4 and a hybridoma which produces an antibody having specific binding affinity to a protein *comprising* SEQ ID NO:3 or SEQ ID NO:4; thus, the written description is not commensurate in scope with the amended claims which read on antibodies and hybridomas producing antibodies that bind to polypeptides comprising SEQ ID NO:3 or SEQ ID NO:4, as well as antibodies and hybridomas producing antibodies that bind to polypeptides comprising *fragments* of SEQ ID NO:3 or SEQ ID NO:4. The amended claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are broadly inclusive of all antibodies that bind to a genus of polypeptides that share a minimum of <u>two</u> consecutive amino acids with SEQ ID NO:3 or SEQ ID NO:4. This rejection could be obviated by amending claims

17-18 to recite "...binding affinity to the AUR1 and/or AUR2..." rather than "...binding affinity to an AUR1 and/or AUR2...".

The rejection of claims 17-18 and newly added claims 29-35 under 35 U.S.C. 103(a), as being unpatentable over Niwa et al (Gene, March 1996, 169:197-201) in view of Campbell ("Monoclonal Antibody Technology", Laboratory Techniques in Biochemistry and Molecular Biology, 1984, 13:1-32), is maintained for reasons of record in the Office Action mailed 7/7/05 and for the reasons set-forth below.

Claims 17-18 are drawn to antibodies having specific binding affinity to proteins encoded by SEQ ID NO:3, antibodies having specific binding affinity to proteins encode by SEQ ID NO:4, hybridomas producing antibodies having specific binding affinity to proteins encoded by SEQ ID NO:3, and hybridomas producing antibodies having specific binding affinity to proteins encoded by SEQ ID NO:4. Newly added claims 29-35 are drawn to monoclonal antibodies and antibodies having specific binding affinity for various domains of AUR1 or AUR2. Since **it is not clear from the specification which sequence encodes AUR1 and which sequence encodes AUR2**, for examination purposes, Examiner is assuming SEQ ID NO:3 encodes both AUR1 and AUR2.

In the Response filed 10/4/05, Applicants argue that the sequence taught by Niwa et al differs significantly from instant SEQ ID NO:3. Applicants further argue that,

due to the differences, an antibody raised against Niwa's sequence would not have "specific binding affinity" for a polypeptide encoded by SEQ ID NO:3. Applicants cite paragraph 46 of US 2004/0265852: "specific binding affinity" means "that the antibody binds to the target (AUR1 and/or AUR2) polypeptide with greater affinity than it binds to other polypeptides under specific conditions". Applicants further state that neither Niwa nor Campbell contains teaching that "bridge the differences between the sequence of Niwa and SEQ ID NO:3 and there is no motivation to do so. Accordingly, the combined references lack the required motivation or suggestion to make the claimed antibodies having specific binding affinity for a polypeptide encoded by SEQ ID NO:3. Even if such a suggestion or motivation did exist, the combined references lack any guidance for doing so. In such a vacuum, the likelihood of success for making the claimed invention would have been zero."

The response filed 10/4/05 has been carefully considered but is deemed not to be persuasive. As demonstrated in the previous Office Action, Niwa et al teach a sequence of significant homology (83.3%) to instant SEQ ID NO:3, with spans of >40 amino acids with 100% homology to segments of instant SEQ ID NO:3. Although Niwa et al does not specifically describe an antibody having specific binding affinity to SEQ ID NO:3 or a hybridoma cell line which produces an antibody having specific binding affinity to SEQ ID NO:3, Campbell teaches (page 29) that it is "customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)".

Further, it is obvious to one of skill in the art to also make polyclonal antibodies for macromolecules, as polyclonal antibodies are easy to produce and provide a probe to study said macromolecule. Additionally, the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APp. & Int. 1990). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the polypeptide sequence taught by Niwa et al for the purposes of generating polyclonal antibodies and generating hybridoma cells that produce monoclonal antibodies that specifically bind to the sequence taught by Niwa et al. One would have been motivated to do so because it is conventional in the art to generate polyclonal antibodies and to generate monoclonal antibodies using hybridoma cells following the cloning of a gene. Further, one of skill in the art would have a reasonable expectation of success in producing the claimed antibodies and hybridoma cells since the production of antibodies and antibody-producing hybridoma cells are well known and conventional in the art. Further, due to the large degree of homology between the sequence taught by Niwa et al and instant SEQ ID NO:3, one of skill in the art would recognize that antibodies raised against Niwa's sequence would have "specific binding affinity" for a polypeptide encoded by instant SEQ ID NO:3, as defined by the specification. One of skill in the art would clearly recognize that antibodies raised against Niwa's sequence would bind to the target (AUR1 and/or AUR2) polypeptide with greater affinity than they would bind to

polypeptides of lesser homology. Further, because of the high degree of homology, there is no reason to "bridge the differences between the sequence of Niwa and SEQ ID NO:3" in order to make the claimed antibodies; the sequence taught by Niwa et al is sufficient to make the claimed antibodies.

In regards to newly added claims 29-35, one of skill in the art would recognize that polyclonal antibodies produced by Niwa's sequence would bind all available epitopes found on SEQ ID NO:3, including those found of the N-terminal, catalytic, and C-terminal domains.

New Rejections

Claim 17 and 29-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite for reciting: "An isolated, enriched or purified antibody....". There appears to be no distinct difference between an *isolated* antibody and a *purified* antibody. To obviate this rejection, Applicant may delete either "isolated" or "purified" from the claim.

Claims 29-34 and 37-42 are indefinite for reciting: "of said AUR1 polypeptide" or "of said AUR2 polypeptide". Throughout the specification, the peptides encoded by

SEQ ID NO:3 or SEQ ID NO:4 are described as "an AUR1 and/or AUR2 polypeptide"; however, it is never made clear which sequence encodes which peptide.

Claims 17 and 29-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Claim 17 recites "An isolated, enriched or purified antibody...". Descriptions of "enriched" *antibodies* are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

Summary

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to

expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a). A shortened statutory period for response to this Final Action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this Final Action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. '1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than six months from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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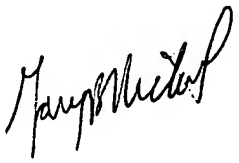

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER